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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/662,777      | 09/15/2003  | Hassan Ahmad         | 2551-1-001          | 1508             |

23565 7590 05/19/2006

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HACKENSACK, NJ 07601

| EXAMINER |
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MCCORMICK EWOLDT, SUSAN BETH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1655

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |                                     |  |
|------------------------------|---|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/662,777      | <b>Applicant(s)</b><br>AHMAD ET AL. |  |
|                              | <b>Examiner</b><br>S. B. McCormick-Ewoldt | <b>Art Unit</b><br>1655             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

The amendment of April 5, 2006 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Election/Restrictions**

Applicant elected Group I and the *Nigella sativa*, in the reply filed February 24, 2005.

Claims 11-25 are withdrawn from further consideration.

**Claims Pending**

Claims 1-2, 4-10 and 26-28 are pending.

**Claim Rejections - 35 USC § 102**

Claims 1-2, 4-10 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Kandil (US 2002/0132019).

Kandil (US 2002/0132019) expressly teaches using *Nigella sativa* in a pharmaceutical composition in an amount of about .1 to about 25% by weight ([0013]). In addition, Kandil discloses the composition can be used in tablets, capsules, liquid, suspensions, nasal forms, suppositories, topical administration and a transdermal patch ([0037], [0039]-[0043]). Therefore, the teaching of Kandil, meet the limitations of claims 1, 2 and 26 and thus anticipates the claimed invention.

**Claim Rejections - 35 USC § 103**

Claims 1-2, 4-10 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kandil (US 2002/0132019).

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Kandil (US 2002/0132019) beneficially discloses using *Nigella sativa* in a pharmaceutical composition in an amount of about .1 to about 25% by weight ([0013]). In addition, Kandil discloses the composition can be used in tablets, capsules, liquid, suspensions, nasal forms, suppositories, topical administration and a transdermal patch ([0037], [0039]-[0043]).

Kandil does not disclose wherein the pharmaceutical composition is used for hepatitis. However, Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

One of ordinary skill in the art would have been motivated to use *Nigella sativa* in a pharmaceutical composition because of the beneficial properties in treating fungal infections. It was clear from the Kandil reference, *Nigella sativa* is used in a pharmaceutical composition to treat fungal infections in an amount of about .1 to about 25% by weight and discloses the composition can be used in tablets, capsules, liquid, suspensions, nasal forms, suppositories, topical administration and a transdermal patch. Therefore, one of ordinary skill in the art would have had a reasonable expectation to use *Nigella sativa* in a pharmaceutical composition because of the beneficial properties in treating fungal infections.

Claims 1-2, 4-10 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medencia (US 5,653,981).

Medencia (US 5,653,981) beneficially discloses using an extract of *Nigella sativa* in a pharmaceutical composition which is effective to increase the immune function and help restore the immune competent cells (column 3, lines 38-42; column 4, lines 14-15). In addition, Medencia also discloses administration of the extract of *Nigella sativa* by itself with an

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appropriate excipient or carrier. It may be administered by such methods as intramuscular, intravenous, subcutaneous, capsules, tablets suppositories or the like (column 5, lines 31-42).

Medencia does not disclose wherein the pharmaceutical composition is used for hepatitis. However, Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

One of ordinary skill in the art would have been motivated to use *Nigella sativa* in a pharmaceutical composition because a therapeutically effective amount of *Nigella sativa* has been used beneficially to increase the immune function and help restore the immune competent cells. It was clear from the Medencia reference that an extract of *Nigella sativa* is in a pharmaceutical composition which is effective to increase the immune function and help restore the immune competent cells and discloses administration of the extract of *Nigella sativa* by itself with an appropriate excipient or carrier. It may be administered by such methods as intramuscular, intravenous, subcutaneous, capsules, tablets suppositories or the like. Therefore, one of ordinary skill in the art would have had a reasonable expectation to use *Nigella sativa* in a pharmaceutical composition to increase the immune function and help restore the immune competent cells.

With regards to the declarations submitted on April 6, 2006, the Examiner has considered the results. However these results are not persuasive because the prior art teaches the same composition as claimed. This is not unexpected because the extract of *Nigella sativa* is taught by the prior art.

#### Summary

No claim is allowed.

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Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

  
CHRISTOPHER R. TATE  
PRIMARY EXAMINER